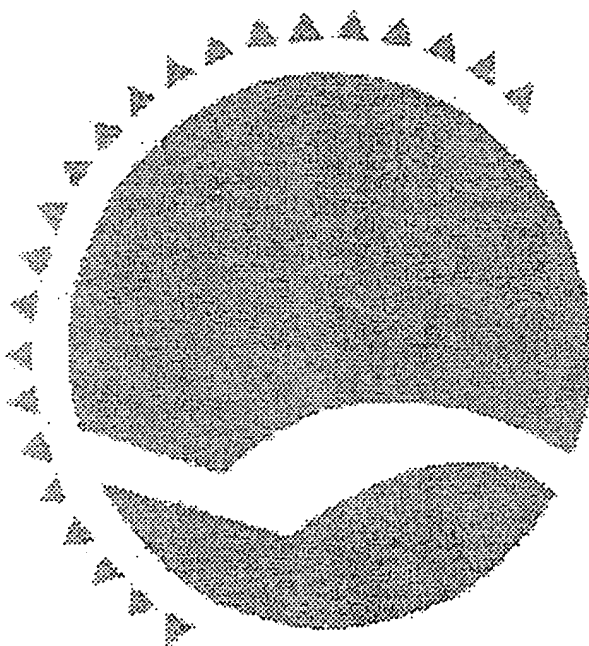


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**ORAL DEPOSITION OF QINGHUA LIU**

**February 7, 2003**

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**CONDENSED TRANSCRIPT AND CONCORDANCE  
PREPARED BY:**

**Sunbelt Reporting & Litigation Services  
(713) 667-0763 Houston  
(214) 747-0763 Dallas**

## Page 1

1 CAUSE NO. 2001-61352  
 2 BAYLOR COLLEGE OF MEDICINE ) IN THE DISTRICT COURT OF  
 3 and BCM TECHNOLOGIES, INC.. )  
 4 )  
 5 Plaintiffs/Counter-defendants.)  
 6 )  
 7 VS. )  
 8 )  
 9 CLONTECH LABORATORIES, INC.. ) HARRIS COUNTY, T E X A S  
 10 )  
 11 Defendant/Counter-plaintiff. )  
 12 )  
 13 VS. )  
 14 )  
 15 INVITROGEN CORPORATION. )  
 16 )  
 17 Additional Counterclaim )  
 18 Defendant. ) 133RD JUDICIAL DISTRICT  
 19 \*\*\*\*\*  
 20 ORAL DEPOSITION OF  
 21 QINGHUA LIU  
 22 February 7, 2003  
 23 \*\*\*\*\*  
 24 Reported By: Taye J. Clark  
 25 Job No. 39664

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1 ORAL DEPOSITION OF  
 2 QINGHUA LIU, produced as a witness at the instance of  
 3 the DEFENDANT/COUNTER-PLAINTIFF, and duly sworn, was  
 4 taken in the above-styled and numbered cause on the 7th  
 5 day of February, from 9:14 a.m. to 10:58 a.m., before  
 6 Taye J. Clark, CSR in and for the State of Texas,  
 7 reported at the offices of Patton Boggs, LLP, 2001 Ross  
 8 Avenue, Suite 3000, Dallas, Texas 75201, pursuant to  
 9 the Texas Rules of Civil Procedure and the provisions  
 10 stated on the record or attached hereto.  
 11  
 12 A P P E A R A N C E S  
 13  
 14 FOR THE PLAINTIFFS/COUNTER-DEFENDANTS:  
 15  
 16 MS. M. MICHELLE MULLER, PH.D.  
 17 Vinson & Elkins  
 18 The Terrace 7  
 19 2801 Via Fortuna, Suite 100  
 20 Austin, Texas 78746-7568  
 21  
 22 FOR THE DEFENDANT/COUNTER-PLAINTIFF:  
 23 MR. MARC R. LABGOLD, PH.D.  
 24 Patton Boggs, LLP  
 25 8484 Westpark Drive  
 McLean, Virginia 22102

## Page 4

1 PRELIMINARY PROCEEDINGS  
 2 THE REPORTER: Going on the record at  
 3 9:14 a.m.  
 4 QINGHUA LIU,  
 5 having been first duly sworn, testified as follows:  
 6 THE REPORTER: By the Rules?  
 7 MR. LABGOLD: Yes.  
 8 THE REPORTER: Do you want to read and  
 9 sign?  
 10 MS. MULLER: Yes.  
 11 MR. LABGOLD: In front of any Notary is  
 12 fine.  
 13 EXAMINATION  
 14 QUESTIONS BY MR. MARC R. LABGOLD:  
 15 Q Good morning, Dr. Liu.  
 16 A Good morning to you, too.  
 17 Q Have you ever been deposed before?  
 18 A No.  
 19 Q Okay. Just so you understand, I'm going to ask  
 20 you some questions, I'm going to show you some  
 21 documents. Hopefully my questions will be clear enough  
 22 that you'll understand.  
 23 If you don't understand the question, just  
 24 ask and I'll try to clarify.  
 25 Your counsel may have certain objections.

## Page 5

1 She'll say, "Objection." The first time she does, I  
2 guarantee you you'll sit there and turn around and look  
3 at her and wait for something else. That's all it is,  
4 she's noting an objection for the record.

5 Unless she instructs you not to answer,  
6 I'll expect an answer to the best of your ability.

7 By whom are you currently employed?

8 A U.T. Southwestern in Dallas.

9 Q Okay. And what's your position there?

10 A Post doctoral fellow.

11 Q In whose lab?

12 A Dr. Xiaodong Wang.

13 Q And what type of work are you doing?

14 A Biochemistry.

15 Q On what type of project?

16 A RNA Interference.

17 Q And how long have you been in your current  
18 position?

19 A Two years.

20 Q And prior to that, am I correctly understanding  
21 you were at Baylor?

22 A Yes.

23 Q And for the entire time you were at Baylor,  
24 were you in Dr. Elledge's lab?

25 A Yes.

## Page 6

1 Q Now, did you prepare -- did you do anything to  
2 prepare for your deposition here today?

3 A You mean the deposition document?

4 Q Did you -- did you meet with your attorneys?

5 A Yes.

6 Q And who did you meet with?

7 A I meet with Michelle and Tracy.

8 Q Okay. And for how long did you meet?

9 A About two --

10 MS. MULLER: I'm going to object on the  
11 basis of privilege.

12 MR. LABGOLD: That's not a privilege.

13 You want me to show you transcripts from  
14 yesterday where I went through the same thing?

15 It's not privileged that you met, it's not  
16 privileged where you met, it's not privileged how long  
17 you met. I'm allowed to ask him as I did for the last  
18 few depositions what documents he reviewed. I'm allowed  
19 to ask if anything refreshes his recollection.

20 I can ask him what he discussed during  
21 those meetings and you can object and instruct him not  
22 to answer, but other than that, I'm entitled to an  
23 answer.

24 Q (By Mr. Labgold) How long did you meet?

25 MS. MULLER: Well, I'm going to have to

## Page 7

1 review that, and if I'm incorrect on that, I will look  
2 at it, but for the moment I'm going to object on the  
3 basis of privilege.

4 MR. LABGOLD: Well, it's not worth my  
5 time, but I will tell you this -- no.

6 Q (By Mr. Labgold) Did you review any documents  
7 during your preparation?

8 A No.

9 Q Other than your meeting with your counsel at  
10 some unidentified undisclosed location -- the vice  
11 president may have been there with you but I won't ask  
12 that because that may also be privileged -- did you do  
13 anything else to prepare to be able to testify here  
14 today?

15 A No.

16 Q Have you spoken to Dr. Elledge anytime in the  
17 past year about the subject of the Univector System or  
18 this laboratory -- or this litigation?

19 A Yes.

20 Q And what were -- what did you discuss with Dr.  
21 Elledge?

22 A I call him, ask him if he knows I have to talk  
23 to you, and he said he knew about it, it's fine.

24 Q Did he tell you that he had had a deposition?

25 A Yes.

## Page 8

1 Q Did he tell you what questions were asked  
2 during that deposition?

3 A No.

4 Q Did you discuss anything else concerning the  
5 deposition or just asking him if it was okay to do a  
6 deposition?

7 A He said, "Answer the question to your best  
8 knowledge, do not make any guess."

9 Q Anything else?

10 A No.

11 Q Now, if I understand correctly, you were one of  
12 the people who contributed to the development of the  
13 Univector System, correct?

14 A Yes.

15 Q And you have prepared a paper which was  
16 published, disclosed in that system, correct?

17 A Yes.

18 Q And you also filed a patent application?

19 A Yes.

20 Q And is it my understanding -- is my  
21 understanding correct that it is you and Dr. Elledge  
22 that created the Univector System?

23 A Yes.

24 Q Now, I understand that Ms. Li was involved in  
25 a -- I don't know how best to describe it -- a variation

## Page 9

1 of the Univector System where it was directed to,  
2 homologous recombination. Is that your understanding?  
3 A It's all part of UPS system.  
4 Q Okay. And is that part of what was in your  
5 patent?  
6 A I don't know.  
7 Q Okay. Now, you collect royalties based on your  
8 contribution, correct?  
9 A Yes.  
10 Q And do you -- what frequency do you receive  
11 checks on that?  
12 A I don't remember.  
13 Q Do you recall how much you've received in  
14 total, approximately?  
15 A I can only estimate, but I'm not going to.  
16 Q Was it \$100,000?  
17 A Less than that.  
18 Q Was it \$50,000?  
19 A It's a couple of thousand dollars, I would say.  
20 Q Just like \$2,000?  
21 MS. MULLER: Objection; form.  
22 A I will say a couple of thousand dollars.  
23 Q (By Mr. Labgold) Okay. Well, I'm trying to get  
24 an idea of what you mean by "a couple."  
25 Colloquially in English, "a couple" would

## Page 10

1 be two?  
2 A Oh, really?  
3 Q Some people would say "a few" is three, but we  
4 might differ on that.  
5 A Approximately \$5,000.  
6 Q And that's the total which you have received to  
7 the best of your understanding?  
8 A Per year.  
9 Q Per year. Okay.  
10 Were you involved in the decision of how  
11 the royalties would be distributed amongst you and your  
12 coinventors?  
13 A No.  
14 Q Let me mark as Lui Exhibit 1 a copy of a BCMT  
15 document bearing production number BCM 001859 through  
16 1664.  
17 (Exhibit No. 1 marked.)  
18 Q (By Mr. Labgold) If you take a look down at the  
19 document about halfway through the page, there's a  
20 heading there that says "Inventors."  
21 A Uh-huh.  
22 Q And then it gives a breakdown between you --  
23 Ms. Li and yourself.  
24 A Uh-huh.  
25 Q And does this comport with your recollection

## Page 11

1 that for 1999 you received approximately \$5,000?  
2 A You mean under the inventors, this part?  
3 Q Yeah.  
4 A Are you saying if the number looks correct?  
5 Q Yeah, your general recollection?  
6 A Yes.  
7 Q Now, do you know why Ms. Li is not named as an  
8 inventor on the patent?  
9 A I don't know.  
10 MS. MULLER: Objection; form.  
11 Q (By Mr. Labgold) Was it your understanding that  
12 your contribution to the development of the Univector  
13 System and Ms. Li's were equivalent?  
14 MS. MULLER: Objection; form.  
15 A Can you rephrase the question?  
16 Q (By Mr. Labgold) Do you believe that Ms. Li  
17 contributed the same amount as you did to the  
18 development of the Univector System?  
19 MS. MULLER: Objection; form.  
20 A No.  
21 Q (By Mr. Labgold) Do you know why, then, Ms. Li  
22 obtains the same royalties as you do?  
23 A I don't know.  
24 Q Have you ever discussed that with Dr. Elledge?  
25 A No.

## Page 12

1 Q Have you ever discussed that with anybody else  
2 at Baylor or BCMT?  
3 A Yes.  
4 THE WITNESS: Is that a privilege?  
5 MS. MULLER: To the extent that you spoke  
6 with counsel or involved communication of counsel, then  
7 I instruct you not to answer.  
8 A That involves discussion with patent counsel at  
9 Baylor.  
10 Q (By Mr. Labgold) Well, at any time did you  
11 raise a concern with anyone at BCMT as to whether the  
12 distribution of royalties was equitable?  
13 MS. MULLER: Again, to the extent that  
14 that requires you to discuss -- to disclose any  
15 conversation with counsel, I instruct you not to answer.  
16 MR. LABGOLD: And Counsel, I would -- I  
17 don't have the energy or the time to deal with this. I  
18 will just note on the record -- and I can tell we're  
19 coming back for another deposition, and it's going to be  
20 on your client's dime.  
21 Because if he's going to Baylor and he's  
22 complaining or inquiring as to why his amount is  
23 equivalent to somebody who joined the project after the  
24 patent was filed, that's not seeking legal counsel.  
25 That's a business dispute.

## Page 13

1 Now, you can instruct him as you will.  
2 I'll give you a moment to think about it. If you're  
3 going to tell me the instruction stands, I'll move on,  
4 and we'll deal with that later.  
5 MS. MULLER: For the moment the  
6 instruction stands.  
7 MR. LABGOLD: Okay.  
8 Q (By Mr. Labgold) Did you ever get an answer as  
9 to why Ms. Li gets the same amount of royalties as you  
10 do dispute -  
11 A No.  
12 Q - the fact that -  
13 Fair enough.  
14 I'd like to mark as Liu Exhibit 2 a copy  
15 of an affidavit which you signed.  
16 (Exhibit No. 2 marked.)  
17 Q (By Mr. Labgold) Can you tell me if you've seen  
18 this document before today?  
19 A Yes.  
20 Q Did you yourself prepare the text of the  
21 document?  
22 A Yes.  
23 Q Did you type it yourself?  
24 A No.  
25 Q So if I understand correctly, you wrote the

## Page 14

1 text of the document and then forwarded it to somebody  
2 else for typing?  
3 MS. MULLER: Objection; privileged.  
4 To the extent that that requires you to  
5 reveal any conversation you had with counsel, again -  
6 MR. LABGOLD: There is nothing privileged  
7 about that. I am entitled to know how he prepared his  
8 declaration, affidavit, whatever you want to call it,  
9 his sworn statement.  
10 Q (By Mr. Labgold) Are you going to -  
11 MS. MULLER: If it involved a conversation  
12 with counsel, I'm going to instruct him not to answer.  
13 MR. LABGOLD: Have you done this before?  
14 MS. MULLER: Sir?  
15 MR. LABGOLD: Have you done this before?  
16 MS. MULLER: I'm not being deposed here.  
17 Q (By Mr. Labgold) When you signed this  
18 affidavit, did you understand that you were under oath?  
19 A Yes.  
20 Q Did you understand what the consequences were  
21 if you made a statement which were not true, to your  
22 knowledge, in a sworn statement?  
23 A Yes.  
24 Q And do you understand that you are under oath  
25 here today, and that if you do not tell the truth, that

## Page 15

1 the penalty of perjury adheres to that?  
2 A Yes.  
3 Q Okay. If you take a look at Paragraph 2 under  
4 Roman numeral two, says: (Reading) I contributed to the  
5 development of the univector plasmid-fusion system.  
6 What was your contribution?  
7 A My contributions to develop the Cre enzyme and  
8 show this concept, this system works in principle.  
9 Q When you say "develop the Cre enzyme," what are  
10 you talking about?  
11 A Making the GST-Cre.  
12 Q So making a GST-Cre fusion, correct?  
13 A No.  
14 Q Please explain.  
15 A Not only that, more than that.  
16 Q Okay. Please explain.  
17 A Making the -  
18 MS. MULLER: Objection; form. I'm sorry.  
19 Go ahead.  
20 A Making a fusion protein, express it, an E.  
21 coli, purify it, demonstrate the purified protein has  
22 high - high specific activity.  
23 Q (By Mr. Labgold) Okay. Now, GST fusion  
24 proteins were known in the art prior to your work,  
25 correct?

## Page 16

1 A Correct.  
2 Q And the Cre enzyme itself was known in the art  
3 prior to your work, correct?  
4 A Correct.  
5 Q And am I correct in understanding that the Cre  
6 recombinases, the Cre enzyme, its ability to recombine  
7 loxP site was also known in the art, correct?  
8 A Correct.  
9 Q If you take a look at page - I'm sorry, we got  
10 a stapling error here.  
11 Actually, looking at Page 2 of your  
12 declaration, and you say that the Univector System was  
13 described and explained in an article and then it sets  
14 forth the article. Do you see that?  
15 A Uh-huh, the first two sentences.  
16 Q Yes. And I'd like to mark - let me give you a  
17 document we've already marked as Elledge Exhibit 3, if  
18 you can confirm for me that is the article to which you  
19 were referring?  
20 A Yes.  
21 Q And when you prepared - let me ask this: Were  
22 you involved in the preparation of the article?  
23 A Yes.  
24 Q And to the best of your ability, did you  
25 completely and fully describe the Univector System in

133<sup>RD</sup> JUDICIAL DISTRICT

**CLONTECH'S MOTION TO SET ASIDE THE CONFIDENTIAL  
DESIGNATION OF CERTAIN DEPOSITION ADMISSIONS  
MATERIAL TO THE PATENTABILITY DETERMINATION  
OF BAYLOR'S PATENT APPLICATION CLAIMS**

t. 

IN THE DISTRICT COURT

OF HARRIS COUNTY, TEXAS

133<sup>rd</sup> JUDICIAL DISTRICT

INVITROGEN CORPORATION,

**Additional Counterclaim Defendant. §**

**OUTSIDE ATTORNEYS' EYES ONLY  
PURSUANT TO PROTECTIVE ORDER**

**CLONTECH'S MOTION TO SET ASIDE THE CONFIDENTIAL  
DESIGNATION OF CERTAIN DEPOSITION ADMISSIONS  
MATERIAL TO THE PATENTABILITY DETERMINATION  
OF BAYLOR'S PATENT APPLICATION CLAIMS**

Defendant/Counterclaim Plaintiff, Clontech Laboratories, Inc. ("Clontech"), moves this Court for an Order to set aside the confidential designation of certain deposition testimony by Plaintiffs/Counterclaim Defendants Baylor College of Medicine and BCM Technologies, Inc. (collectively "Baylor") witnesses Drs. Elledge and Kreuzer and Ms. Li. This relief is sought to permit Clontech to inform the U.S. Patent and Trademark Office ("PTO") of material admissions made by these witnesses, pursuant to Baylor's obligations under 37 C.F.R. § 1.56.

## BACKGROUND

In 1996, Drs. Stephen J. Elledge ("Elledge"), a Baylor professor, along with Qinghua Liu and Mamie Li, allegedly developed certain technology to facilitate rapid subcloning, referred to as the "Univector system." In 1997, the inventors filed a patent application in the PTO

disclosing the Univector system. That patent application matured into U.S. Patent No. 5,851,808 ("the '808 patent") on December 22, 1998. Baylor filed at least one continuation-in-part patent application from the application that matured into the '808 patent, i.e., U.S. Serial No. 09/122,384 ("the '384 application"). Baylor is believed to be the assignee of the '384 application.

Throughout discovery, Clontech repeatedly requested all documents concerning the '808 patent, which document requests encompassed any continuations and continuations-in-part thereof. On December 3, 2002, Clontech filed a motion to compel production of such documents. Clontech again explicitly requested all documents related to any continuation applications following the April 14, 2003 deposition of Charles Lipsey, during which Baylor's questioning implied that one or more continuation applications may be pending. (Ex. 1, Clontech's April 14, 2003 letter).

At the April 28, 2003 pretrial conference, the Court instructed the parties to inform the Special Master that all discovery motions should be decided promptly, by May 9, 2003. After the parties did so, counsel for Baylor agreed, for the first time, to provide the long requested discovery pertaining to the '808 patent. (Exs. 2 & 3, Ltrs. from Blanke to Oparil, May 2, 2003 and May 6, 2003).

On May 6, 2003, Baylor belatedly provided a letter to Clontech enclosing a Notice of Allowability in the '384 application, which was mailed by the PTO on April 22, 2003. (Ex. 4 hereto). Baylor also provided other documents to Clontech on May 15, 16, and 19, 2003 (received by Clontech on May 16, 17 and 20, 2003), which included information disclosed to the PTO.



The information Baylor provided to Clontech does not indicate that Baylor alerted the PTO to the existence of: (1) this litigation, (2) the Declaratory Judgment suit Clontech filed against Baylor – now dismissed – in the U.S. District Court for the Southern District of Texas, or (3) the deposition testimony that is material to the patentability of Baylor's claims.

### ARGUMENT

Individuals owe the PTO a duty of candor & good faith. See 37 C.F.R. § 1.56. ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." "[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of patentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes"). To comply with this duty under 37 C.F.R. § 1.56, applicants and applicants' representatives must disclose (1) the existence of litigation, and (2) any material information arising from that litigation related to the subject matter of the patent application, including deposition testimony. See, e.g., *Environ Products v. Total Containment, Inc.*, 43 U.S.P.Q. 2d 1288 (E.D. Pa. 1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp.2d 508 (D. N.J. 1999); see generally, Manual of Patent Examination Procedure ("MPEP") Section 2001.06(c).<sup>1</sup>

<sup>1</sup> "Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the Patent and Trademark Office. Examples of such material information include evidence of possible prior use or sales, questions of inventorship, prior art, allegations of 'fraud,' 'inequitable conduct,' and 'violation of duty of disclosure.' Another example of such material information is any assertion that is made during litigation which is contradictory to assertions made to the examiner. *Environ Prods., Inc. v. Total Containment, Inc.*, 43 U.S.P.Q. 2d 1288, 1291 (E.D. Pa. 1997). Such information might arise during litigation

The documents Baylor recently provided to Clontech include disclosures to the PTO, but do not include any disclosure of this ongoing litigation, the Federal Court Declaratory Judgment litigation or any disclosure of critical admissions that occurred in depositions taken during discovery in this case.

Clontech is bound by the protective order in this case, not to disclose information contained in the depositions designated as confidential pursuant to the protective order. (Ex. 5, Order dated October 28, 2002). Baylor has utilized this protective order to designate much of the information disclosed as "confidential" or "outside attorneys eyes only", and has designated the testimony of its witnesses as confidential, except that of Dr. Liu. Because Dr. Liu's testimony was not designated as being confidential, Clontech filed a Protest in the PTO with respect to the '384 application, disclosing relevant portions of Dr. Liu's transcript and the existence of this case (Ex. 6). As explained in the Protest, Dr. Liu admits, *inter alia*, that at the time of filing the application that led to the '808 patent (and, therefore, necessarily before filing the '384 invention therefrom), GST fusion proteins were known and the Cre enzyme was known:

Q: Okay. Now, GST fusion proteins were known in the art prior to your work, correct?

A: Correct.

Q: And the Cre enzyme itself was known in the art prior to your work, correct?

A: Correct.

Q: And am I correct in understanding that the Cre recombinases [sic recombinase], the Cre enzyme, its ability to recombine loxP site [sic sites] was also known in the art, correct?

A: Correct.

(Ex. 7, Liu Dep. at 15:23-16:8).

These admissions are material to the patentability of, for example, claims 43, 46, 48, 49, 52-54, 56 and 63 as they appear in the Preliminary Amendment that Baylor sent Clontech, which

---

in, for example, pleadings, admissions, discovery including interrogatories, depositions, and other documents, and testimony." MPEP § 2001.06(c).

appear to have the same claim numbering as the allowed claims on the Notice of Allowability.

(Ex. 4).

Additional admissions, which are believed to be material to the patentability of at least one of the claims, were made during the depositions of Drs. Elledge and Kreuzer and Ms. Li. Clontech cannot provide this information marked confidential to the PTO; however, Baylor can and should do so. In the event that Baylor does not comply with its duty of candor to the PTO, this Court should permit Clontech to provide the relevant portions of deposition transcripts to the PTO, notwithstanding the protective order. In particular, Baylor's witnesses admitted the following:

1. The Cre enzyme was known in the prior art to the filing of the application that matured into the '808 patent. (Li Dep. at 20:20-25, 22:21-23:10; Liu Dep. at 15:23-17:17; Elledge TRCP 199.2(b)(1) Dep. at 65:1-4; Elledge 2003 Dep. at 22:11-23:20; Kreuzer Dep. at 59:11-23).<sup>2</sup>
2. Elledge and Liu did not invent Cre. (Kreuzer Dep. at 59:11-23).
3. Each of the components of the Univector system was in the public domain prior to the filing of the application that matured into the '808 patent. (Liu Dep. at 15; Elledge 2003 Dep. at 22:11-23:20; Li Dep. at 20-24, 37, 39; Kreuzer Dep. at 55-56, 59).
4. Each of the components of the Univector system was in the public domain prior to any alleged invention of that system by Drs. Elledge and/or Liu. (Liu Dep. at 15; Elledge 2003 Dep. at 22:11-23:20; Li Dep. at 20-24, 37, 39; Kreuzer Dep. at 55-56, 59).
5. Cre-mediated recombination was in the public domain prior to the filing of the application that matured into the '808 patent. (Elledge TRCP 199.2(b)(1) Dep. at 65:1-4; Elledge 2003 Dep. at 22:11-23:20; Kreuzer Dep. at 75:2-78:23; Liu Dep. at 15:23-17:17).

---

<sup>2</sup> Relevant excerpts from the Li deposition are attached as Ex. 8; relevant excerpts from the Elledge depositions are attached as Ex. 9; and relevant excerpts from the Kreuzer deposition are attached as Ex. 10.

6. Cre-mediated recombination using *lox P* sites was in the public domain prior to the filing of the '808 patent application. (Elledge TRCP 199.2(b)(1) Dep. at 65:1-4; Elledge 2003 Dep. at 22:11-23:20; Kreuzer Dep. at 75:2-78:23; Liu Dep. at 15:23-17:17; Li Dep. at 20:20-25, 21:5-8).
7. *Lox P*-recombination was in the public domain prior to the filing of the '808 patent application. (Elledge TRCP 199.2(b)(1) Dep. at 65:1-4; Liu Dep. at 15:23-17:17; Elledge 2003 Dep. at 22:11-23:20; Kreuzer Dep. at 80:12-82:33; Li at 20:20-25, 21:5-8).
8. GST-fusion proteins were in the public domain prior to the filing of the '808 patent application. (Kreuzer Dep. at 59:11-23; Li Dep. at 22:21-23:10; Liu Dep. at 15:23-17:17).
9. Conditional origins of replication were in the public domain prior to the filing of the '808 patent application. (Elledge TRCP 199.2(b)(1) Dep. at 66:20-22; Elledge 2003 Dep. at 22:11-23:20; Kreuzer at 55:11-56:5).
10. The use of a conditional origin of replication as a selection means was in the public domain prior to the filing of the '808 patent application. (Elledge 2003 Dep. at 22:11-23:20; Kreuzer at 55:11-56:5; Li Dep. at 39:2-15).
11. Subcloning was in the public domain prior to the filing of the '808 patent application. (Elledge 2003 Dep. at 24:8-25:18).
12. Subcloning using plasmids was in the public domain prior to the filing of the '808 patent application. (Elledge 2003 Dep. at 24:8-25:18).
13. Subcloning using restriction modification of plasmids was in the public domain prior to the filing of the '808 patent application. (Elledge 2003 Dep. at 24:8-25:18).

Clontech requests this Court permit it to provide the above-referenced material to the PTO and thereby permit to PTO to properly examine the patent application at issue.

The prosecution documents Baylor recently provided to Clontech indicate that Baylor's claim scope has varied tremendously during the prosecution of the '384 application. In fact, vastly different claims were pursued in this application and were allowed twice, twice being withdrawn from issuance before canceling all of the claims and adding the new claims in the October 3, 2002 Preliminary Amendment. The prosecution history also shows a restriction

requirement, which could very well indicate that one or more divisional applications have been or will be filed pursuing claims of a different scope than those claims presently allowed. Accordingly, the protective order should be set aside for the sole purpose of providing material to the PTO not just with respect to the information material to what may be the presently allowed claims (the scope of which Clontech has no way of confirming), but also with respect to all other admissions that are material to claims Baylor may attempt to add to this or a divisional or continuing application, based on the disclosure of the '384 application.

Thus, this Court should set aside the protective order with respect to all of the above information, and any additional information, which is material to the patentability of any potential claims Baylor presently or may pursue, which Baylor is required to submit to the PTO pursuant to its obligations under 37 C.F.R. § 1.56.

#### CONCLUSION

For all the foregoing reasons, Clontech's motion should be granted.

Dated: May 23, 2003

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By: 

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Clontech Laboratories, Inc.

**CERTIFICATE OF SERVICE**

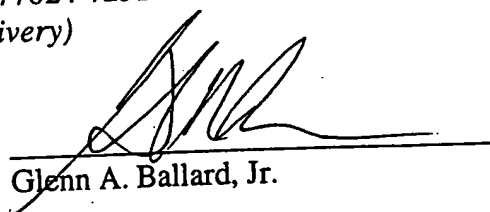
The undersigned hereby certifies that they caused the foregoing to be served on May 23,

2003, on the following:

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Glenn A. Ballard, Jr.



US005851808A

## United States Patent [19]

Elledge et al.

[11] Patent Number: 5,851,808

[45] Date of Patent: Dec. 22, 1998

[54] RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION

[75] Inventors: Stephen J. Elledge; Qinghua Liu, both of Houston, Tex.

[73] Assignee: Baylor College of Medicine

[21] Appl. No.: 864,224

[22] Filed: Feb. 28, 1997

[51] Int. Cl.<sup>6</sup> ..... C12N 5/09; C12N 15/63; C12N 15/64; C12N 15/66

[52] U.S. Cl. .... 435/172.3; 435/320.1; 536/23.1

[58] Field of Search ..... 435/320.1, 172.3; 536/23.1

[56] References Cited

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5,102,797 4/1992 Tucker et al. .... 435/172.3

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(List continued on next page.)

Primary Examiner—Johnny F. Railey, II

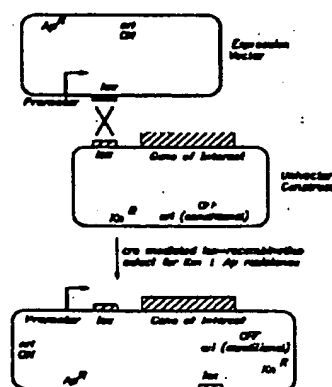
Attorney, Agent, or Firm—Medlen &amp; Carroll, LLP

[57]

## ABSTRACT

The present invention provides compositions, including vectors, and methods for the rapid subcloning of nucleic acid sequences in vivo and in vitro. In particular, the invention provides vectors used to contain a gene of interest that comprise a sequence-specific recombinase target site. These vectors are used to rapidly transfer the gene of interest into any expression vector that contains a sequence-specific recombinase target site located downstream of a promoter element so that the gene of interest may be expressed.

24 Claims, 11 Drawing Sheets





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April 14, 2003

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**VIA FACSIMILE**

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Austin, Texas 78746

Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc. v. Invitrogen Corp.*  
Cause No. 2001-61352

Dear David:

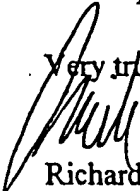
Further to my request at the conclusion of the April 14, 2003 deposition of Charles Lipsey, please provide us with the following documents immediately:

- (1) the exhibits marked at Ruo Bo Zhang's deposition, and
- (2) all documents relating to all continuations from or other U.S. patent applications related to the '808 patent

With regard to the latter request, we are aware that at least one such continuation application exists. In particular, as shown on the enclosed Patent Application Information Retrieval search of continuity data, U.S. Patent Application 09/122,384 is a pending continuation application from the application that matured into the '808 patent. Clontech long ago requested information pertaining to Baylor's '808 patent. Baylor chose to object to providing such information and required Clontech to file a (pending) Motion to Compel. As demonstrated in the questions you posed to Mr. Lipsey, these documents are relevant to the claims and defenses in this action.

Please let us know when we may expect to receive the requested documents.

Very truly,

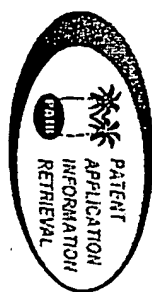
  
Richard J. Oparil  
Enclosures

cc: Glenn A. Ballard, Jr., Esq.

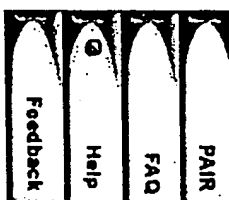


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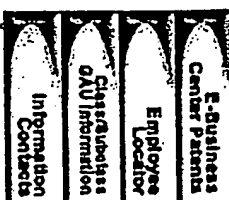
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Application Number:	08/864,224	Class / Sub-Class:	435/172.300
Filing or 371(c) Date:	02-28-1997	Location:	-
Issue Date of Patent:	12-22-1998	Status:	-
Examiner Name:	RAILEY, JOHNNY	Group Art Unit:	1636
Earliest Publication No.:	-	Attorney Docket	BCM-02681
Earliest Publication	-	Customer Number:	-
Confirmation Number:	6512		

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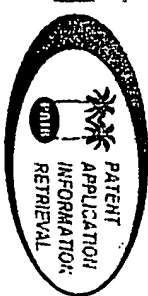
Child Continuity Data

09/122,384 filed on 07-24-1998 which is Pending claims the benefit of 08/864,224

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Filing or 371(c) Date:	02-28-1997	Class / Sub-Class:	435/172.300
Issue Date of Patent:	12-22-1998	Location:	-
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Group Art Unit:	1636	Attorney Docket	BCM-02681
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May 2, 2003

*By Fax*

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2550 M Street NW  
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Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc.;*  
Cause No. 2001-61352

Dear Richard:

I am writing to confirm what I believe is our agreement to considerably narrow the issues raised in Clontech's Motion to Compel Discovery from Baylor. Below I will refer to the headings in the motion and recount what I understand to be the agreement.

***"Baylor Should be Compelled to Produce Documents Regarding the Reorganization of BCMT and BCM's Office of Technology Administration."*** We have are reconfirmed that there are no such documents.

***"Baylor Should be Compelled to Confirm that the Files of Certain Baylor Employees and/or Former Employees Have Been Searched and Responsive Documents Produced."*** ***"Baylor Should be Compelled to Confirm that Certain Relevant Locations at Baylor Have Been Searched and All Responsive Documents Produced."*** We have confirmed that the records of the persons listed in the motion have been searched, as have the locations specified in the motion.

***"Baylor Should be Compelled to Produce Its Documents Pertaining [to] the Harvard FLEXGene Consortium."*** We agreed to determine whether Baylor has a copy of Invitrogen's proposal or any documents relating to such proposal. We have confirmed that Invitrogen never provided its Harvard FLEXgene Consortium application or response to request for proposal to Baylor nor did Baylor correspond with Invitrogen or have any other communication with Invitrogen about the Consortium.

Mr. Richard J. Oparil

Page 2

May 2, 2003

***"Baylor Should be Compelled to Produce All Slides, Notes and Similar Material Presented at Conferences or Other Public Events Pertaining to the Elledge Technology."*** We have reconfirmed that there are no such materials. In doing so, we obtained and reviewed the Medlen & Carroll firm's records.

***"Baylor Should be Compelled to Produce All 1998 Calendars of Drs. Elledge, Li, and/or Liu Relating to the Elledge Technology."*** We are determining whether such calendars exist for Drs. Elledge and Li. If so, we will produce the entries that pertain to any presentation of the Univector System or circulation of it to researchers. As I explained on the telephone, we do not have possession, custody, or control of Dr. Liu's calendar.

***"Baylor Should be Compelled to Produce All Documents Relating to the '808 Patent."*** We are reexamining these requests. We will produce all non-privileged responsive documents relating to the '808 patent and any related applications.

***"Baylor Should be Compelled to Produce All of Its Responsive Lab Notebooks and Other Documents Sought in Request for Production No. 2."*** We have confirmed that all responsive notebooks have been produced. The complete record of the development of the Univector System is set forth in Dr. Liu's lab notebook and in other records of the Elledge laboratory, which were produced early in the litigation. The bates range of the Liu notebook is BCM 658-939. A comprehensive search of the Elledge laboratory's records were made and all other relevant pages from the laboratory notebooks of Dr. Elledge, Dr. Liu and Mamie Li were provided at bates ranges BCM 393-657 and 940-1027.

***"Baylor Should be Compelled to Fully Respond to Requests for Production Nos. 15 and 16."*** We are reconfirming that nothing further exists and will then write to confirm as much or produce what non-privileged documents that may be located.

***"Baylor Should be Compelled to Produce Documents Responsive to Request for Production No. 17."*** Clontech withdraws this request from the motion.

***"Baylor Should be Compelled to State the Dates of Disclosure of Information that Baylor Alleges are Trade Secrets."*** The interrogatory response will be amended to include dates or approximate time frames (if no specific date can be determined), based on the marketing log and other records, some of which are in Clontech's files.

***"Baylor Should be Compelled to Supplement its Incomplete Responses to Interrogatories Nos. 4, 11 and Any Other Interrogatories for Which Baylor Withheld Information Relating to the '808 Patent."*** We will amend the response to the interrogatory to refer Clontech to the marketing log. Interrogatory No. 11 will be amended to specify that Drs. Elledge and Liu are the inventors (as the '808 patent reflects).

Mr. Richard J. Oparil

Page 3

May 2, 2003

***"Baylor Should be Compelled to Supplement its Incomplete Response to Interrogatory No. 7, and All Other Interrogatories That Were Not Fully Responded to Because No Protective Order Was in Place."*** Clontech has deposed each of the Baylor and Invitrogen participants in those negotiations. Baylor has produced its marketing log, which details those discussions. And Invitrogen produced other materials that you used at the recent Invitrogen depositions. I have confirmed that no information was withheld on the basis that there was, at the time of the interrogatory, no protective order. With this confirmation, I understand Clontech withdraws its request for a supplemental response to interrogatory nos. 4, 5, and 7.

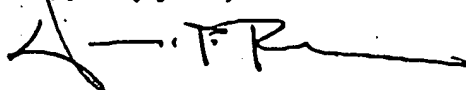
***"Baylor Should be Compelled to Fully Respond to Interrogatory Nos. 8 and 9."*** Baylor will amend its response to refer Clontech to the royalty reports (most of which are exhibits to the initial Baylor depositions).

***"Baylor Should be Compelled to Either Produce the Documents Requested in Clontech's July 30, 2002 Letter or Confirm that all Responsive Documents Have Been Produced."*** We are reconfirming that there are no additional non-privileged responsive documents. We will then write to confirm as much or produce what non-privileged documents that may be located.

***"Baylor Should be Compelled to Produce Responsive Internal Communications."*** We have reconfirmed that there are no additional responsive, non-privileged documents.

If the foregoing is correct, please countersign this letter and return it to our offices. We will tend to filing the letter with the Court, see TEX. R. CIV. P. 11, and circulating a copy to Jack Goldstein.

Very truly yours,



David P. Blanke

AGREED:

---

Richard J. Oparil

*Attorney for Clontech Laboratories, Inc.*

other discovery materials, whether produced informally or in response to interrogatories, requests for admissions, requests for production of documents or other formal method of discovery.

1.2 This Protective Order shall also govern any designated record of information produced in this action pursuant to required disclosures under any Texas State procedural rule or Harris County District Court local rule, and any supplementary disclosures thereto.

1.3 This Protective Order shall apply to the parties and any nonparty from whom discovery may be sought and who desires the protection of this Protective Order.

## **2. Designation.**

2.1 Each party shall have the right to designate as confidential and subject to this Protective Order any information produced by it in this action which contains, reflects, or otherwise discloses confidential technical, business or financial information ("CONFIDENTIAL information"). This designation shall be made by stamping or otherwise labeling each page or thing containing confidential information with the legend CONFIDENTIAL prior to its production or, if inadvertently produced without such legend, by furnishing written notice to the receiving party that the information shall be considered confidential under this Protective Order. The parties will use reasonable care to avoid designating any documents or information CONFIDENTIAL that are generally available to the public.

2.2 Each party shall have the right to designate as restricted to review by those categories of individuals listed in ¶ 4.1, excluding ¶ 4.1(d), 4.1(e) and 4.1(f), and subject to this Protective Order any information produced in this action which contains, reflects, or otherwise discloses trade secrets, current research and development information or competitively sensitive information, ("OUTSIDE ATTORNEY'S EYES ONLY information"). To the extent that



material is marked OUTSIDE ATTORNEY'S EYES ONLY, such material shall be revealed to or used by limited categories of individuals, as provided for in ¶ 4.2, and shall not be communicated in any manner, either directly or indirectly, to any person or entity not permitted disclosure pursuant to this Protective Order. Any copies of such material, abstracts, summaries or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed OUTSIDE ATTORNEY'S EYES ONLY, and the same terms regarding confidentiality of these materials shall apply as apply to the originals. Use of this highly restrictive designation is limited to information of the highest, competitive sensitivity. The parties will use reasonable care to avoid designating any documents or information OUTSIDE ATTORNEY'S EYES ONLY for which the designating party does not have a good faith belief that the documents or information satisfy the criteria set forth in this ¶ 2.2. OUTSIDE ATTORNEY'S EYES ONLY information shall be used only for purposes directly related to this action, and for no other purpose whatsoever, except by consent of all of the parties or order of the Court.

2.3 To the extent that either party has, prior to the date that this Order is entered, produced to the other side materials that the producing party has marked with any confidentiality designation, all such materials shall be considered to have been designated under this Order as OUTSIDE ATTORNEY'S EYES ONLY unless otherwise agreed by the Parties.

### 3. Limit On Use And Disclosure Of Designated Information.

3.1 Each party and all persons bound by the terms of this Protective Order shall use any information or document governed by this Protective Order only in connection with the prosecution or defense of this action, except by consent of the parties or order of the Court. No party or other

person shall disclose or release to any person not authorized under this Protective Order any information or document governed by this Protective Order for any purpose, or to any person authorized under this Protective Order for any other purpose.

3.2 It is, however, understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated confidential information received by the party, provided that such rendering of advice and opinions shall not reveal the content of such information except by prior written agreement with counsel for the producing party.

3.3 The attorneys of record for the parties and other persons receiving information governed by this Protective Order shall exercise reasonable care to insure that the information and documents governed by this Protective Order are (a) used only for the purposes specified herein, and (b) disclosed only to authorized persons.

#### 4. Disclosure Of Confidential Material.

4.1 Documents or information designated CONFIDENTIAL shall be disclosed by the recipient thereof, on a need-to-know basis, only to:

a. the attorneys who are actively involved in this action and who are partners or associates of the following law firms, which are trial counsel or attorneys of record for the parties, and their employees: (i) Bracewell & Patterson LLP; (ii) Patton Boggs LLP; and (iii) Vinson & Elkins LLP.

b. the Court and Court personnel, as provided in ¶ 12;

c. consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who are agreed upon by the parties pursuant to ¶ 6, who are not employees or otherwise affiliated with either of the parties (except persons scheduled to be deposed

by either of the parties pursuant to Rule 30(b)(6), Fed.R.Civ.P.), and who first agree to be bound by the terms of this Protective Order;

d. Clontech's (or its successor-in-interest) in-house counsel not involved in the preparation or prosecution of patent applications and/or competitive decision making, provided that each individual must first agree to be bound by the terms of this Protective Order and shall be given access to such documents and information only at the offices of his respective attorneys of record as set forth in § 4.a. Copies of such documents and information are not given to any of the people to be taken off the premises of the party's counsel;

e. Baylor's in-house counsel not involved in the preparation or prosecution of patent applications and/or competitive decision-making, provided that each individual must first agree to be bound by the terms of this Protective Order and shall be given access to such documents and information only at the offices of his respective attorneys of record as set forth in § 4.a. Copies of such documents and information are not given to any of the people to be taken off the premises of the party's counsel;

f. Invitrogen's in-house counsel not involved in the preparation or prosecution of patent applications and/or competitive decision-making, provided that each individual must first agree to be bound by the terms of this Protective Order and shall be given access to such documents and information only at the offices of his respective attorneys of record as set forth in § 4.a. Copies of such documents and information are not given to any of the people to be taken off the premises of the party's counsel;

g. court reporters employed in connection with this action; and

h. outside copying and computer services necessary for document handling, and other litigation support personnel (e.g., graphic designers and animators).

4.2 Documents or information designated **OUTSIDE ATTORNEY'S EYES ONLY** shall be disclosed by the recipient thereof, on a need-to-know basis, to those categories of individuals listed in ¶ 4.1, excluding ¶ 4.1(d), 4.1(e) and 4.1(f).

## **5. Redaction.**

Counsel for a party producing documents may mask ("redact") material deemed exempt from discovery because it is protected from disclosure under the attorney-client privilege or work product immunity afforded by Rule 26(b), Fed.R.Civ.P. and/or Texas Rule of Civil Procedure. However, any document from which material is masked must identify in the masked area that masking or redaction has occurred. The reason for any such masking must be stated on a log to be provided within thirty (30) days after the production of the documents. Sufficient information regarding the masked material must be provided to the other party to enable it to evaluate the legitimacy of the asserted privilege or immunity. The parties reserve the right to pursue categories for redaction in addition to those identified above, by either consent of the parties or order of the Court, to be addressed on a case-by case basis.

## **6. Identification Of Experts.**

6.1 If any party desires to disclose information designated **CONFIDENTIAL** or **OUTSIDE ATTORNEY'S EYES ONLY** to any expert or consultant pursuant to ¶ 4 above, it must first identify in writing to the attorneys for the producing party each such expert or consultant. The attorney for the producing party shall have five (5) business days from receipt of such notice to object to disclosure of such information to any of the experts or consultants so identified.

6.2 Such identification shall include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date curriculum vitae identifying at least all other present and prior employments or consultancies of the expert or consultant in the field, and a list of the cases in which the expert or consultant has testified at a deposition or at trial within the last four years. The parties shall attempt to resolve any objections informally. If the objections cannot be resolved, the party seeking to disclose the CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information to the expert or consultant may move the Court for an Order allowing the disclosure. In the event objections are made and not resolved informally, disclosure of information to the expert or consultant shall not be made except by Order of the Court (or to any limited extent upon which the parties may agree).

7. Agreement Of Confidentiality.

In no event shall any information designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY be disclosed to any person authorized pursuant to ¶ 4, other than (a) the Court and Court personnel, (b) the parties' attorneys (excluding in-house counsel) and their authorized secretarial and legal assistant staffs, (c) court reporters, and (d) outside copying and computer services necessary for document handling, until such person has executed a written Confidentiality Undertaking (in the form set forth in Exhibit A hereto) acknowledging and agreeing to be bound by the terms of this Protective Order. Copies of such Confidentiality Undertakings shall be promptly served on the producing party.

### **8. Related Documents.**

Information designated **CONFIDENTIAL** or **OUTSIDE ATTORNEY'S EYES ONLY** shall include (a) all documents, copies, extracts, and complete or partial summaries prepared from or containing such information; (b) portions of deposition transcripts and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (c) portions of briefs, memoranda or any other papers filed with the Court and exhibits thereto which contain or reflect the content of any such documents, copies, extracts, or summaries; (d) deposition testimony designated in accordance with ¶ 9; and (e) testimony taken at a hearing or other proceeding that is designated in accordance with ¶ 10.

### **9. Designation Of Deposition Transcripts.**

9.1 Deposition transcripts, or portions thereof, may be designated as subject to this Protective Order either (a) at the time of such deposition, in which case the transcript of the designated testimony shall be marked by the reporter with the appropriate legend (see ¶ 2.1) as the designating party may direct, or (b) within thirty (30) days following taking of the deposition by providing written notice to the reporter and all counsel of record, in which case all counsel receiving such notice shall mark the copies or portions of the designated transcript in their possession or under their control as directed by the designating party.

9.2 All deposition transcripts not previously designated shall be deemed to be, and shall be treated as, **OUTSIDE ATTORNEY'S EYES ONLY** for a period of thirty (30) days after the taking of the deposition, and the transcript shall not be disclosed by a non-designating party to persons other than those persons named or approved according to ¶ 4.

9.3 The designating party shall have the right to exclude from a deposition, before the taking of testimony which the designating party designates **CONFIDENTIAL** or **OUTSIDE ATTORNEY'S EYES ONLY** and subject to this Protective Order, all persons other than those persons previously qualified to receive such information pursuant to ¶ 4.

#### **10. Designation Of Hearing Testimony Or Argument.**

With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of **CONFIDENTIAL** or **OUTSIDE ATTORNEY'S EYES ONLY** information, counsel may designate on the record prior to such disclosure that the disclosure is subject to confidentiality restrictions. Whenever matter designated **CONFIDENTIAL** or **OUTSIDE ATTORNEY'S EYES ONLY** is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the hearing or other proceeding any person who is not entitled under this Order to receive information so designated.

#### **11. Disclosure To Author Or Recipient.**

Notwithstanding any other provisions of this Order, nothing herein shall prohibit counsel for a party from disclosing a document containing information designated **CONFIDENTIAL** or **OUTSIDE ATTORNEY'S EYES ONLY** to any person which the document clearly identifies as an author, addressee, or carbon copy recipient of such document, or to any current employee of the producing party. During deposition or trial testimony, counsel may disclose documents produced by a party to current employees and officers of the producing party. And regardless of such designation pursuant to this Protective Order, if a document or testimony makes reference to the actual or alleged

conduct or statements of a person who is a potential witness, counsel may discuss such conduct or statements with such witness without revealing any portion of the document or testimony other than that which specifically refers to such conduct or statement, and such discussion shall not constitute disclosure in violation of this Protective Order.

**12. Designation Of Documents Under Seal**

Any information designated OUTSIDE ATTORNEY'S EYES ONLY, if filed with the Court, shall be filed under seal and shall be made available only to the Court and to persons authorized by the terms of this Protective Order. The party filing any paper which reflects, contains or includes any OUTSIDE ATTORNEY'S EYES ONLY information subject to this Protective Order shall file such paper in a sealed envelope, or other appropriately sealed container, which indicates the title of the action, the party filing the materials, the nature of the materials filed, the appropriate legend (see ¶ 2.1), and a statement substantially in the following form:

**This envelope contains documents subject to a Protective Order of the Court. It should be opened only by the Court. Its contents should not be disclosed, revealed or made public except by Order of the Court or written agreement of the parties.**

**13. Confidentiality Of Party's Own Documents.**

No person may disclose, in public or private, any designated information of another party except as provided for in this Protective Order, but nothing herein shall affect the right of the designating party to disclose to its officers, directors, employees, attorneys, consultants or experts, or to any other person, its own information. Such disclosure shall not waive the protections of this Protective Order and shall not entitle other parties or their attorneys to disclose such information in violation of it, unless by such disclosure of the designating party the information becomes public



knowledge (see ¶ 16). Similarly, the Protective Order shall not preclude a party from showing its own information to its officers, directors, employees, attorneys, consultants or experts, or to any other person, which information has been filed under seal by the opposing party.

**14. Other Protections.**

14.1 No person shall use any CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information, or information derived therefrom, for purposes other than the prosecution or defense of this action, including without limitation, for purposes of preparing, filing or prosecuting any patent application, continuation or divisional patent application, reissue patent application or request for re-examination.

14.2 Any party may mark any document or thing containing CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information as an exhibit to a deposition, hearing or other proceeding and examine any witness thereon qualified under the terms of this Protective Order to have access to such designated material.

**15. Challenge To Confidentiality.**

15.1 This Protective Order shall not preclude any party from seeking and obtaining, on an appropriate showing, such additional protection with respect to the confidentiality of documents or other discovery materials as that party may consider appropriate. Nor shall any party be precluded from (a) claiming that any matter designated hereunder is not entitled to the protections of this Protective Order, (b) applying to the Court for an Order permitting the disclosure or use of information or documents otherwise prohibited by this Protective Order, or (c) applying for a further Order modifying this Protective Order in any respect. No party shall be obligated to challenge the

propriety of any designation, and failure to do so shall not preclude a subsequent challenge to the propriety of such designation.

15.2 On any motion challenging the designation of any information, the burden of proof shall lie with the producing party to establish that the information is, in fact, **CONFIDENTIAL** or **OUTSIDE ATTORNEY'S EYES ONLY** information. If a party seeks declassification or removal of particular items from a designation on the ground that such designation is not necessary to protect the interests of the party wishing the designated information, the following procedure shall be utilized:

a. The party seeking such declassification or removal shall give counsel of record for the other party written notice thereof by facsimile, with confirmation by mail or by personal delivery, specifying the designated information as to which such removal is sought and the reasons for the request; and

b. If, after conferring, the parties cannot reach agreement concerning the matter within five (5) business days after the delivery and receipt of the notice, then the party requesting the declassification or removal of particular items may file and serve a motion for a further Order of this Court directing that the designation shall be so removed.

#### 16. Prior Or Public Knowledge.

This Protective Order shall not apply to information that, prior to disclosure, is public knowledge, and the restrictions contained in this Protective Order shall not apply to information that is, or after disclosure becomes, public knowledge other than by an act or omission of the party to whom such disclosure is made, or that is legitimately and independently acquired from a source not subject to this Protective Order.

**17. Limitation Of Protective Order.**

This Protective Order is not intended to address discovery objections to produce, answer, or respond on the grounds of attorney-client privilege or work product immunity, or to preclude either party from seeking further relief or protective orders from the Court as may be appropriate under the Federal Rules of Civil Procedure.

**18. Other Proceedings.**

18.1 By entering this order and limiting the disclosure of information in this case, the court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who may be subject to a motion to disclose another party's CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information pursuant to this order shall promptly notify that party of the motion so that it may have an opportunity to appear and be heard on whether such information should be disclosed.

**19. Inadvertent Disclosure Of Work Product Or Privileged Information: Procedure And Waiver.**

19.1 The producing party shall promptly notify the receiving party in writing in the event of an inadvertent production of documents subject to work product immunity or the attorney-client privilege after the producing party learns of such inadvertent production.

19.2 If prompt notification is made and the producing party establishes the circumstances surrounding the document's inadvertent production, such inadvertently produced document and all copies thereof shall be returned to the producing party or destroyed, upon request.

19.3 No use shall be made of such documents during deposition or at trial, nor shall they be shown to anyone who was not given access to them prior to the request to return or destroy them.

19.4 If, after conferring, the parties are unable to reach a satisfactory agreement within five (5) business days of receipt of the request to return or destroy them, the producing party may move the Court regarding the matter within ten (10) business days after conferring.

19.5 The non-producing party shall not disclose the document for which the belated claim of immunity or privilege is being made to any person, other than those persons who have had it in their possession prior to receipt of notification from the producing party, until the expiration of the ten (10) day period identified in ¶ 19.4 or, if a motion to the Court is submitted, until disposition of that motion. Upon being notified by the producing party pursuant to ¶ 19.1, counsel for the non-producing party shall use his or her best efforts to retrieve all copies of the documents at issue.

19.6 Following expiration of the fifteen (15) day term, nothing in this Protective Order shall preclude either party from moving the Court for return or destruction of later discovered, inadvertently produced work product immunity or attorney-client privileged documents.

## 20. Non-Party Material.

The terms of this Protective Order, as well as the terms of any protective order that may be entered into between a discovering party and third party for the production of information to the discovering party, are applicable to CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY information provided by a non-party. Information provided by a non-party in connection with this action and designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY, pursuant to the terms of this Protective Order shall be protected by the remedies and relief provided by this Protective Order.

**21. Return Of Designated Information.**

Upon final termination of this action, unless otherwise agreed to in writing by an attorney of record for the designating party, each party shall assemble and return, or certify destruction of, all materials containing information designated CONFIDENTIAL or OUTSIDE ATTORNEY'S EYES ONLY, including all copies, extracts and summaries thereof, to the party from whom the designated material was obtained, except that (a) any documents or copies which contain, constitute or reflect attorney's work product or attorney-client privilege communications, and (b) archive copies of pleadings, motion papers, deposition transcripts, correspondence and written discovery responses may be retained by counsel.

**22. Waiver Or Termination Of Order.**

No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this action, but shall continue until further Order of this Court.

**23. Modification Of Order; Prior Agreements.**

This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further Order of the Court. This Protective Order supersedes any agreements between the parties regarding the confidentiality of particular information entered into before the date of this Protective Order.

24. Section Captions.

The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

Dated: August \_\_, 2002

**BRACEWELL & PATTERSON LLP**

By: 

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APPROVES AS TO FORM:

Dated: August 28, 2002

*afh*

VINSON & ELKINS LLP

By: 

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Houston, Texas 77002-6760

IT IS SO ORDERED:

*Signed*  
Dated: August 28, 2002



UNITED STATES DISTRICT JUDGE PRESIDING

CAUSE NO. 2001-61352

BAYLOR COLLEGE OF MEDICINE and  
BCM TECHNOLOGIES, INC.,

PLAINTIFFS/COUNTERCLAIM DEFENDANTS,

v.

CLONTECH LABORATORIES, INC.,

DEFENDANT/COUNTERCLAIM PLAINTIFF,

INVITROGEN CORPORATION,

ADDITIONAL COUNTERCLAIM DEFENDANT,

IN THE DISTRICT COURT

HARRIS COUNTY, TEXAS

133<sup>RD</sup> JUDICIAL DISTRICT

**CONFIDENTIALITY UNDERTAKING**

I certify that I have read the Stipulated Protective Order in this action and that I fully understand the terms of the Order. I recognize that I am bound by the terms of that Order, and I agree to comply with those terms. I hereby consent to the personal jurisdiction of the Harris County District Court for any proceedings involving the enforcement of that Order.

EXECUTED this \_\_\_\_\_ day of \_\_\_\_\_, 2002.

\_\_\_\_\_  
Name

\_\_\_\_\_  
Affiliation

\_\_\_\_\_  
Business Address

**EXHIBIT A**



**EXPEDITED PROCEDURE REQUESTED  
PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Elledge et al.	)	Examiner: James S. Ketter
	)	
USSN: 09/122,384	)	Art Unit: 1636
	)	
For: Rapid Subcloning Using Site-Specific Recombination	)	Filed: July 24, 1998
	)	

**PROTEST AGAINST PENDING APPLICATION UNDER 37 C.F.R. § 1.291**

Honorable Commissioner for Patents  
Mail Stop Petitions  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Clontech Laboratories, Inc. ("Clontech") hereby petitions the Commissioner to initiate a protest against pending application number 09/122,384 under 37 C.F.R. § 1.291.

**I. SUBJECT MATTER DISCLOSED IN U.S. SERIAL NO. 09/122,384 IS THE SUBJECT MATTER OF LITIGATION**

Clontech is in litigation against BCM Technologies, Inc. and Baylor College of Medicine (collectively "BCM"), who are believed to be the assignee of USSN 09/122,384 ("the '384 application") over an alleged theft of trade secrets. The case is in the Texas 133<sup>rd</sup> Judicial District Court in Harris County, Texas, Cause No. 2001-61352.

Clontech repeatedly requested all documents concerning U.S. Patent No. 5,851,808 ("the '808 patent"), the patent that issued from the parent application to the '384 application, which document requests encompass any continuations and continuations-in-part thereof. Clontech

again explicitly requested all documents related to any continuation applications following the April 14, 2003 deposition of Charles Lipsey (the April 14, 2003 letter requesting such documents is attached as Ex. 1 hereto), during which BCM's questioning implied that one or more continuation applications may be pending. BCM has repeatedly ignored such demands and failed to provide such documents until recently, after the close of discovery in the pending litigation. BCM's conduct is the subject of a motion to compel in the Texas Court.

On May 6, 2003, after the close of discovery, litigation counsel for BCM belatedly provided a letter to Clontech enclosing a Notice of Allowability of USSN 09/122,384, which was mailed in late April (Ex. 2 hereto). BCM also provided other documents to Clontech on May 16 and 17, 2003, indicating information disclosed to the Office.

The information BCM provided to Clontech does not indicate that BCM alerted the Office to the case *Baylor College of Medicine et al. v. Clontech Laboratories, Inc. v. Invitrogen Corp.* case in the Texas 133<sup>rd</sup> Judicial Court in Harris County, Texas. (A copy of Plaintiff's First Amended Petition is attached hereto as Ex. 3). This case is related to the subject matter of the '384 application and the '808 patent. Nor does the information provided by BCM indicate that BCM alerted the Office to the declaratory judgment action filed in the U.S. District Court for the Southern District of Texas on January 4, 2002, alleging *inter alia*, the invalidity and non-infringement of the '808 patent. (A copy of the Complaint For Declaratory Judgment is attached hereto as Ex. 4). The latter federal case was only recently dismissed on April 7, 2003 (Ex. 5), as a result of BCM's motion to dismiss along with its Covenant Not To Assert The '808 Patent (Ex. 6), which were also not brought to the attention of the Office.

Under 37 C.F.R. § 1.56, applicants and applicants' representatives must disclose (1) the existence of litigation and (2) any material information arising from that litigation related to the

subject matter of the patent application, including, for example, deposition testimony. *See, e.g.,* MPEP 2001.06(c); *Environ Products v. Total Containment, Inc.*, 43 U.S.P.Q. 2d 1288 (E.D. Pa. 1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F. Supp.2d 508 (D.N.J. 1999).

The documents BCM recently provided to Clontech from the PTO prosecution include disclosures of some prior art to the Office, but do not include any disclosure of the ongoing litigation and do not include any disclosure of critical admissions that occurred in depositions taken during discovery. The submitted documents also do not include any disclosure of the dismissed litigation and covenant not to assert the '808 patent.

## **II. THIS PROTEST INVOLVES INFORMATION THAT CANNOT BE ADEQUATELY ADDRESSED WITH REEXAMINATION**

Our request for a Protest can only be addressed before issuance because the standard and type of prior art that may be considered will change after issuance. During examination, the Office need only show by a preponderance of the evidence that an application is unpatentable. Once a U.S. patent is issued, any challenge must be supported by clear and convincing evidence. While an issued U.S. patent can be reexamined, a reexamination can only consider patents and printed publications and only address issues arising under sections 102 or 103 of Title 35. BCM should not be permitted to benefit from its refusal to disclose information to the USPTO and to Clontech in a timely manner.

Clontech is bound by a protective order in the ongoing Texas litigation. This protective order bars Clontech from disclosing BCM information and deposition transcripts if BCM has designated them as confidential. BCM has utilized this protective order to designate much of the information disclosed as confidential and has designated all of its witnesses' deposition

testimony as confidential, except that of Dr. Liu. Consequently, Clontech cannot describe any admissions that might be present in other depositions that have occurred, including the depositions of Drs. Elledge and Kreuzer and Ms. Li. Nevertheless, Clontech can disclose that the deposition transcript which BCM did not designate as confidential -- that of Dr. Liu -- contains admissions that are material to the patentability of the claims that were provided in the preliminary amendment of October 3, 2002. Claim numbers corresponding to those claims have now been allowed.

The deposition of Dr. Liu admits that at the time of filing of the application that led to the '808 patent (and therefore, necessarily before filing the '384 application therefrom), GST fusion proteins were known and the Cre enzyme was known:

Q: Okay. Now, GST fusion proteins were known in the art prior to your work, correct?

A: Correct.

Q. And the Cre enzyme itself was known in the art prior to your work, correct?

A. Correct.

Q. And am I correct in understanding that the Cre recombinases [sic recombinase], the Cre enzyme, its ability to recombine loxP site [sic sites] was also known in the art, correct?

A. Correct.

(Liu Dep. at 15:23-16:8, Ex. 7).

These admissions appear material to the patentability of for example claims 43, 46, 48, 49, 52-54, 56 and 63 as those claims appear in the Preliminary Amendment that BCM disclosed to Clontech. These claim numbers are those that appear to correspond to the allowed claims on the Notice of Allowability. (Ex. 1).

While Clontech cannot provide information marked confidential to the Office, BCM can provide this information to the PTO. This information can be supplied as part of BCM's Duty of Disclosure under Rule 1.56, or it can be provided in response to a direct request from the Examiner under 37 C.F.R. § 1.105.

The review under 37 C.F.R. § 1.291 represents the PTO's last opportunity to consider information contained in the deposition transcripts. Once the 09/122,384 patent issues, the PTO will not be able to provide any meaningful review of the deposition transcript admissions. As indicated by Assistant Deputy Commissioner Kunin, "[t]he PTO has an obligations to issue patents that meet the statutory requirements for patentability." *Blacklight Power, Inc. v. Rogan*, 295 F.3d 1269, 1271 (Fed. Cir. 2002) (affirming the PTO's decision to cancel issuance of a patent after allowance and after the issue fee was paid). Moreover, the PTO is vested with broad "latitude to withdraw an application from issue without a final determination of unpatentability when the exigencies of time do not allow for such determination." *Id.* at 1272.

### **III. THE PTO SHOULD PERMIT THE INITIATION OF A PROTEST OR STAY ISSUANCE OF A PATENT ON THE '384 APPLICATION**

The PTO should initiate a Protest, based on the failure of BCM to alert the agency to ongoing litigation related to the '384 application and the failure of BCM to provide the PTO with material deposition admissions. In the alternative, the PTO should stay issuance of the '384 application until the Judge in the Texas 133<sup>rd</sup> Judicial District Court rules on Clontech's Motion to De-designate Certain Deposition Admissions Material to the Patentability Determination of Baylor Patent Application Claims and permits the PTO Examiner to review the deposition testimony. Clontech is presently preparing a motion to de-designate the transcripts or portions thereof that contain admissions material to the patentability of the '384 application. This motion will be submitted to the Judge, who will determine if this information can be provided to the PTO to permit the PTO to perform its mission.

This Protest has been served upon applicants via their representative in accordance with 37 CFR § 1.248 as well as being filed in duplicate with the PTO. Proof of service is attached as Exhibit 8 hereto.

The U.S. Patent and Trademark Office is hereby authorized to charge any fees that may be required in conjunction with this submission to Deposit Account Number 50-2228.

Respectfully submitted,



Scott A. Chambers  
Reg. No. 37,573

PATTON BOGGS, LLP  
8484 Westpark Drive, 9<sup>th</sup> Floor  
McLean, Virginia 22102  
Phone: (703) 744-8000  
Fax: (703) 744-8001

## CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2003 I caused to be delivered by fax and FED EX a copy of  
**PROTEST AGAINST PENDING APPLICATION UNDER 37 C.F.R. § 1.291** and exhibits  
1-8 thereto relating to USSN 09/122,384, addressed to the attorney of record in that matter as  
follows:

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I declare under penalty of perjury that the foregoing is true and correct.

A handwritten signature in cursive script, appearing to read "Scott H. Chandler", written over a horizontal line.